

the following rejections under 35 USC §112, first paragraph, are alleged:

- (1) Claim 22 is rejected and the specification objected to for lack of written description of amino acid "X" (final action, paragraph 5, bridging pages 3-4 thereof).
- (2) The specification is rejected alone under §112, first paragraph, for lack of utility with respect to treatment of cancer (final action, paragraph 4, bridging pages 2-3 thereof).

If the examiner intends that additional rejections be maintained, it is respectfully requested that the examiner clarify those rejections to be maintained specifically by dispatch of a second advisory action.

I. *REJECTION OF CLAIM 22 AND OBJECTION TO SPECIFICATION, UNDER 35 USC §112, 1ST PARAGRAPH*

(a) Claim 22 is adequately described and fully enabled by the specification; moreover it does not claim a fragment containing "X".

The examiner states that:

"simply removing the seq.[uences] that contain X does not overcome the rejection because the [written description] rej.[ection sic, objection] was to the spec.[ification] where X is not adequately defined. Also seq. ID #2 contains X"

(Advisory Action, 2/25/94). Without conceding to the examiner's allegation regarding lack of written description with respect to the term "X," applicants, for the sake of expedient prosecution, again have amended claim 22 so that it now excludes claiming a fragment containing an amino acid designated as "X." Hence the rejection of claim 22 is rendered moot.

The examiner states further, however, that objection to the *specification* based upon its use of the term X is maintained. This rejection is improper, since there is no legal requirement that the specification must provide written description for subject matter that is *not claimed*.

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The basis for the rejection of the specification, the statute 35 USC §112, first paragraph, requires that, "[t]he specification shall contain a written description of the invention ... as to enable any [skilled] person ... to make and use the same ..." (emphasis added). In that statute's second paragraph, "the invention" is defined as the claimed invention, to wit: "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which applicant regards as his invention." Thus, "the invention" referred to in the first paragraph is indeed, the *claimed invention*.

The written description requirement is a separate and distinct requirement from that of enablement (how to make and use) also under 35 USC §112 first paragraph. Moreover, it is an established principle of case law that is determined with respect to the claimed invention¹. In contrast to the well-established precedent, the examiner objects to certain contents of the specification which are not claimed.

¹ Plastic Container Corp. v. Continental Plastics of Oklahoma, Inc., 607 F.2d 885, 203 USPQ 27 (10th Cir. 1979), cert. denied, 444 U.S. 1018 (1980), *on remand*, 515 F. Supp. 834, 214 USPQ 530 (W.D. Okla. 1980), *aff'd in part & rev'd in part*, 708 F.2d 1554 (10th Cir. 1983) ("To satisfy the description requirement of this section of the statute, an application must contain sufficient disclosure, expressly or inherently, to make it clear to one skilled in the art that the patentee was in possession of the claimed subject matter at the time of the filing of the application."); *May v. Carriage Inc.*, 688 F. Supp. 408, 416, 7 USPQ2d 1593, 1600 (N.D. Ind. 1988) ("The test is whether the specification would have reasonably conveyed to one of ordinary skill that the inventor invented the later-claimed subject matter."); *Phillips Petroleum Co. v. U.S. Steel Corp.*, 673 F. Supp. 1278, 6 USPQ2d 1065, 1068 (D. Del. 1987), *aff'd*, 865 F.2d 1247, 9 USPQ2d 1461 (Fed. Cir. 1989) ("The focus . . . is whether the claimed subject matter is adequately described.")

Applicants request that the Examiner state specifically what statutory, administrative or judicial basis is relied on to support this rejection of the specification. Applicants are familiar with administrative precedent based upon 35 USC §101, which permit the examiner, on a discretionary basis, to require cancelation from the specification a non-claimed subject matter disclosing an unbelievable utility on its face. *In re Gottlieb et al.* 140 USPQ 665. However, to applicants' knowledge, there is no known basis for requiring cancellation of material on the alleged basis that of lack of written description, where that subject matter is not claimed.

(b) To a skilled scientist, the specification contains disclosure sufficient to show that the applicants possessed the claimed subject matter, as well as the non-claimed subject matter, at the time of filing.

The examiner alleges that there is a lack of written description with regard to the amino acid sequences which comprise amino acids designated as "X". As stated above, these sequences are not even claimed, therefore, no written description requirement exists with respect to this terminology for the examiner to enforce. Nonetheless, were they claimed, applicants would maintain that these sequence are sufficiently described in the specification, in a manner such that the knowledgeable reader would recognize that applicants possessed the non-claimed subject matter.

An appreciation that only the four amino acids, asparagine, threonine, serine or possibly, hydroxylysine are glycosylated in mammalian cells, with asparagine being the most predominately glycosylated amino acid, is gained readily by access to a basic level college textbook, MOLECULAR BIOLOGY OF THE CELL, Alberts et al. Garland Publishing, NY, pp. 345-346 [Appendix A]. Thus, a scientist would know to expect that an asparagine residue would function, most likely, as an amino acid in position "X" and thus would not dispute that the

applicants had possession of the invention. Even still, such a scientist would expect that applicants could have readily determined empirically which of the four possible residues could function in position X.

II. *REJECTION OF SPECIFICATION
UNDER 35 USC §112, 1ST PARAGRAPH*

The examiner has objected to the specification for failing to enable a method for using the claimed invention as a therapeutic agent. While the examiner recognizes that the specification enables the use of the present invention as a diagnostic agent, the examiner objects to the specification under 35 USC § 112, first paragraph, "'in relation to the treatment of cancer'" (Final Official Action at page 3). Applicants respectfully traverse this rejection on the grounds that it is improper.

In the present instance, applicants point out first, that no therapeutic use is *claimed*. Enablement, as well as the written description requirement under 35 USC §112 first paragraph as discussed above, is determined relative to the claimed invention². Once again, the basis for the examiner's rejection contradicts well-established precedent.

Furthermore, there is no allegation in the disclosure that cancer is cured. Applicants are aware of patents, too numerous to cite, where compounds used for the *treatment* of cancer are

² DeGeorge v. Bernier, 768 F.2d 1318, 226 USPQ 758 (Fed. Cir. 1985); Cross v. Iiazuka, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985); Christianson v. Colt Industries Operating Corp., 822 F.2d 1544, 1562, 3 USPQ2d 1241, 1254 (Fed. Cir. 1987), *vacated and remanded with instructions to transfer appeal to Court of Appeals for the Seventh Circuit*, 108 S. Ct. 2166, 7 USPQ2d 1109 (1988). ("The requirement for disclosure of sufficient information to enable one skilled in the art to practice the best mode of the *claimed* invention is and has been proven fully adequate for over 150 years." [no emphasis added])

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claimed. For treatment of cancer, the instant specification is believable in the absence of any specific reasoning to the contrary posed by the examiner. Nevertheless, should the examiner wish applicants to expunge material from the specification, the examiner is respectfully requested to point out which disclosure is offensive and to provide a specific, non-speculative basis why that disclosure is unbelievable on its face.

Accordingly, this enablement rejection, which is not directed to the claimed invention, properly should be withdrawn. Further, as presented, the rejection is speculative and untenable. Thus, applicants request reconsideration and withdrawal of the rejection.

In view of the foregoing amendments and remarks, applicants submit that all of the active claims are now in condition for allowance. Early notification to that effect is earnestly solicited. Should there be any further matter requiring consideration, Examiner Huff is invited to contact the undersigned counsel.

It is believed that no additional fees are required; however, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 19-0741.

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It is further believed that no additional petition for an extension of time under 37 C.F.R. § 1.136 is required. However, should such a petition be required, applicant hereby petitions the Commissioner for an extension of time, and authorizes the Commissioner to charge the necessary petition fee to Deposit Account No. 19-0741.

Respectfully submitted,

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